UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,334	02/11/2005	Benjamin Oshlack	200.1156US	6951

23280 7590 06/24/2009

Davidson, Davidson & Kappel, LLC
485 7th Avenue
14th Floor
New York, NY 10018

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,334	OSHLACK ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16,17 and 53-60* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14,16,17 and 53-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment, remarks, and RCE, all filed on 13 April 2009.
- The remarks filed on 13 April 2009 have been considered but are moot in view of the new grounds of rejection.
- All references applied in this Office action are currently of-record.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 13 April 2009 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-3, 5-7, 10-14, 16, 17, 53-55, 57, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,639,476 ("Oshlack") in view of US 6,136,345 ("Grimmett"), further in view of US 2003/0191147 (“Sherman”).

Independent claim 1 recites a pharmaceutical formulation comprising: a substrate comprising one therapeutic agent consisting of an opioid antagonist; the substrate overcoated with a diffusion barrier coating comprising an anionic polymer and a plasticizer; and a coating comprising a hydrophobic material and an erosion-promoting agent coated over said diffusion barrier coating.

Oshlack teaches a solid controlled release formulation having a coating derived from a hydrophobic acrylic polymer and a substrate including an active agent (see abstract), reading on instant claims 1, 7, and 57. The acrylic coating may further comprise a plasticizer, reading on instant claim 1 (see col. 12, line 33). The active agent may be coated a core, such as a pharmaceutically acceptable bead (see col. 5, lines 58-60 and col. 15, line 58), reading on instant claims 2 and 3. The acrylic polymer coating is present in an amount of about 2 to 25% of the weight of the substrate (see col. 6, line 5); a range that overlaps with that recited in instant claim 10. The substrate may comprise a multi-particulate system, reading on instant claims 12 and 13. The coating may provide controlled release of the therapeutic agent (see, e.g., col. 6, line 1), reading on instant claim 14. The concentration of plasticizer included in the acrylic polymer coating is about 1 to 50% (see col. 12, line 54), reading on claim 55. The coating may comprising a passageway (see col. 11, line 49), reading on claim 56.

Oshlack explains that the disclosed formulation is beneficial because it provides a stable dissolution of the active agent which is unchanged after exposure to accelerated storage conditions (see abstract).

Oshlack differs from the instant application in that it does not teach a coating made of hydrophobic material over the anionic polymer coating. However, such a coating was known in the art at the time the instant application was filed, as shown by Grimmett (see col. 1, lines 37-41). The outer layer may be comprised of a cellulosic polymer (see col. 4, line 48), reading on instant claim 16, and may comprise an erosion promoting agent, such as starch or gum, reading on instant claims 1, 54, and 57.

Oshlack further differs from the instant application in that it does not teach an opioid antagonist. However, use of opioid antagonists such as naltrexone (see [0058]) (reading on instant claims 1, 17, 53, and 60) in formulations such as coated granules (see [0080]) comprising a coating layer (see [0134]) made of, e.g., a cellulosic polymer (see [0135]) was known in the art at the time the instant application was filed, as shown by Sherman. The dose of opioid antagonist is at a therapeutically effective amoutn, reading on instant claim 11 (see claim 98). Naltrexone is inherently protonated, reading on instant claim 5. Protonated compounds inherently have an affinity for anionic polymers, reading on instant claim 6.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a pharmaceutical formulation comprising: a substrate comprising one therapeutic agent consisting of an opioid antagonist; the substrate overcoated with a diffusion barrier coating comprising an anionic polymer and a

plasticizer; and a coating comprising a hydrophobic material and an erosion-promoting agent coated over said diffusion barrier coating, as taught by Oshlack in view of Grimmett, further in view of Sherman. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides a stable dissolution of the active agent which is unchanged after exposure to accelerated storage conditions, as explained by Oshlack (see above).

*

2. Claims 1, 4, 58, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,639,476 ("Oshlack") in view of US 6,136,345 ("Grimmett"), further in view of US 2003/0191147 ("Sherman"), further in view of WO 01/58447 ("Oshlack II").

Oshlack, Grimmett, and Sherman are discussed above. These references differ from the instant application in that they do not teach the matrix multiparticulates of instant claim 4, the immediate release matrices of instant claim 58, and the compressed multiparticulate matrix of instant claim 59.

Oshlack II teaches a controlled-release dosage form containing an opioid agonist and an opioid antagonist (see abstract). The active agent may be located in a controlled-release matrix bead formulation (see page 27, lines 30-31; page 32, line 22). The active may also be incorporated in an immediate release matrix (see page 42, lines 7-9). The multiparticulate system may be compressed (see, e.g., Example 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a pharmaceutical formulation comprising: a matrix

multiparticulate substrate comprising one therapeutic agent consisting of an opioid antagonist, the substrate comprising a compressed immediate release multiparticulate matrix; the substrate overcoated with a diffusion barrier coating comprising an anionic polymer and a plasticizer; and a coating comprising a hydrophobic material and an erosion-promoting agent coated over said diffusion barrier coating, as taught by Oshlack in view of Grimmett, further in view of Sherman, further in view of Oshlack II. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides a stable dissolution of the active agent which is unchanged after exposure to accelerated storage conditions, as explained by Oshlack (see above).

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615